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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,122	08/10/2006	Barry Peter Liversidge	1926-00120	5703

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EXAMINER

PATEL, SHEFALI DILIP

ART UNIT	PAPER NUMBER
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3767

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07/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/589,122	Applicant(s) LIVERSIDGE, BARRY PETER	
	Examiner SHEFALI D. PATEL	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/10/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file: GB 0403335.3, filed in Great Britain on February 14, 2004.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-3, 8-14, 17-19, 21-28, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jangula (US 2005/0171484), and further in view of Sempere (EP 409180 A1).

In regards to claims 1-3, 11, 12, 18, and 19, Jangula teaches a handling device (Figures 2-4) for use with a medical injector (syringe [90]) having a cylindrical body provided with a boss at the forward end thereof supporting a forwardly-projecting needle furnished with a protective sheath (needle cap [92]), which device comprises:

a. a carrier [10] having an outer cylindrical wall and co-axial therewith an inner tube (spring nut [52]) which is a close sliding fit over the protective sheath [92] of a needle (Figure 4)

- b. a cylindrical sleeve (bushing [46]) slidably mounted within the outer cylindrical wall of the carrier [10], the rear end of the sleeve [46] being adapted to receive the cylindrical body of the injector [90]
- c. a bushing (cap [30] and adaptor [40]) slidably located within the cylindrical sleeve [46], which bushing [30][40] is retained within the sleeve [46] and defines a bore (openings [33][44]) for receiving the boss at the forward end of the injector body [90]
- d. spring means on the inner tube (spring nut [52]) urging the bushing [30][40] towards the rear end of the sleeve [46] (paragraph [0027])
- e. a plug (body [12]) slidably mounted on the carrier [10] and projectable from the forward end thereof, the forward end of the protective sheath [92] of a received injector [90] engaging the plug [12] (Figure 4)
- f. whereby in use the device (Figures 2-4) is fitted to the forward end of an injector [90] by receiving the injector cylindrical body in the sleeve [46] and the boss in the bore [33][44] of the bushing [30][40], the sheath [92] then coupling to the inner tube [52] of the carrier [10] and the forward end of the sheath [52] engaging the plug [12] so pushing the plug [12] forwardly with respect to the carrier [10] to project therefrom, and on subsequent withdrawal of the carrier [10] from the injector [90], the sheath [92] remains within the carrier [10] (paragraph [0028])

Jangula does not teach that on subsequent withdrawal of the carrier [10] from the injector [90], the bushing [30][40] and sleeve [46] remain on the injector. Sempere teaches a handling device (Figures 1-6) that is connected to a medical injector (syringe [4]) in which on withdrawal of a carrier (external cover [9]) of the device, a bushing (body [2]) and sleeve (body [1]) of the device

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remain on the injector [4]. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the bushing and sleeve of the device of Jangula to remain upon the injector upon withdrawal of the carrier, as taught by Sempere, as the needle of the injector, subsequent to removal of the sheath from the needle, will be protected by the shielding effect of the bushing and sleeve upon the injector (Figure 1), before and after the injector is used (column 1, lines 4-12).

From Applicant's specification (page 8, line 15), the spring means is performed by a helical compression spring [29].

In regards to claim 8, in a modified device of Jangula and Sempere, Jangula teaches that the plug [12] has an enlarged head (leg [16]) at its forward end which lies externally of the carrier [10] (Figure 4).

In regards to claim 13, in a modified device of Jangula and Sempere, Jangula teaches that the plug [12] has a rearwardly-facing socket (cavity [25]) within which the forward end of the needle sheath [92] of an injector [90] is receivable (Figures 2-5).

In regards to claim 17, in a modified device of Jangula and Sempere, Jangula is silent about whether the plug [12] is of a contrasting color to that of the carrier [10]. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the plug with a contrasting color to that of the carrier because Applicant has not disclosed that contrasting colors provide an advantage, are used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the plug and the carrier being the

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same color because regardless of color, the plug will still perform the function of closing the open forward end of the device. Therefore, it would have been an obvious matter of design choice to modify Jangula, in a modified device of Jangula and Sempere, to obtain the invention as specified in claim 17.

In regards to claim 21-23, 26, 27, 30, and 31, Jangula teaches a handling device (Figures 2-4) for use with a medical injector (syringe [90]) having a cylindrical body provided with a boss at the forward end thereof supporting a forwardly-projecting needle furnished with a protective sheath (needle cap [92]), which device comprises:

- a. a carrier [10] having an outer cylindrical wall and co-axial therewith an inner tube (spring nut [52]) which is a close sliding fit over the protective sheath [92] of a needle (Figure 4)
- b. a cylindrical sleeve (bushing [46]) slidably mounted within the outer cylindrical wall of the carrier [10], the rear end of the sleeve [46] being adapted to receive the cylindrical body of the injector [90]
- c. a bushing (cap [30] and adaptor [40]) slidably located within the cylindrical sleeve [46], which bushing [30][40] is retained within the sleeve [46] and defines a bore (openings [33][44]) for receiving the boss at the forward end of the injector body [90]
- d. spring means on the inner tube (spring nut [52]) urging the bushing [30][40] towards the rear end of the sleeve [46] (paragraph [0027])
- e. whereby in use the device (Figures 2-4) is fitted to the forward end of an injector [90] by receiving the injector cylindrical body in the sleeve [46] and the boss in the bore

[33][44] of the bushing [30][40], the sheath [92] then coupling to the inner tube [52] of the carrier [10], and on subsequent withdrawal of the carrier [10] from the injector [90], the sheath [92] remains within the carrier [10] (paragraph [0028])

Jangula does not teach that on subsequent withdrawal of the carrier [10] from the injector [90], the bushing [30][40] and sleeve [46] remain on the injector. Sempere teaches a handling device (Figures 1-6) that is connected to a medical injector (syringe [4]) in which on withdrawal of a carrier (external cover [9]) of the device, a bushing (body [2]) and sleeve (body [1]) of the device remain on the injector [4]. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the bushing and sleeve of the device of Jangula to remain upon the injector upon withdrawal of the carrier, as taught by Sempere, as the needle of the injector, subsequent to removal of the sheath from the needle, will be protected by the shielding effect of the bushing and sleeve upon the injector (Figure 1), before and after the injector is used (column 1, lines 4-12).

From Applicant's specification (page 8, line 15), the spring means is performed by a helical compression spring [29].

In regards to claims 9, 10, 24, and 25, in a modified device of Jangula and Sempere, Jangula teaches that the rear end of the sleeve [46] has an internal profile which includes one or more radially-inwardly directed nibs (inward extending stop surfaces [48] with which the bushing [30][40] is engageable (Figure 4).

In regards to claims 14 and 28, in a modified device of Jangula and Sempere, Jangula does not teach that the spring means is a helical compression spring, as Jangula teaches that the

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inner tube (spring nut [52]) itself urges the bushing [30][40] towards the rear end of the sleeve [46] (paragraph [0027]). Sempere teaches that a helical compression spring (compression spring [8] located within the sleeve (body [1]) acts between the sleeve [1] and the bushing (body [2]) (Figures 1-3). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to substitute the spring action of the inner tube of the modified device of Jangula and Sempere with the helical compression spring, as taught by Sempere, as the spring will cause the bushing to be forwardly displaced with respect to the sleeve to provide a shielding effect to the needle, before and after the injector is used (column 2, lines 38-54).

4. Claims 4-7 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jangula and Sempere, as applied to claims 1 and 2 above, and further in view of Brunnberg et al (US 2006/0100588).

In regards to claims 4-7 and 16, in a modified device of Jangula and Sempere, Jangula does not teach that the plug [12] is supported within the carrier [10] or located inside of the carrier, as Jangula teaches that the plug is supported outside of the carrier (Figure 4). Brunnberg et al teaches a handling device (Figure 3, device [10]) wherein a plug (push button [54]) is slidably supported within a carrier (housing [12])(paragraph [0040]). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to substitute the plug, in the modified handling device of Jangula and Sempere, with the plug, as taught by Brunnberg et al, as such will enable the plug to function as a push button to eject the needle sheath from the device (paragraph [0044]) and back onto the needle of the injector after use of the injector in order to prevent contamination of the environment by the used needle.

5. Claims 15 and 29 rejected under 35 U.S.C. 103(a) as being unpatentable over Jangula and Sempere, as applied to claims 1 and 21 above, and further in view of Pizzino (US 4,702,737).

In regards to claims 15 and 29, in a modified device of Jangula and Sempere, Jangula is silent about whether the boss of the injector [90] is externally screw-threaded, for use with a needle having a hub with an internally-threaded socket co-operable with the threads of the boss. Pizzino teaches an injector (Figure 1, syringe [10]) having a boss (externally screw threaded tubular conduit [46]) with external screw threads that are co-operable with the internal screw threads of a hub (internally screw threaded hub [52]) of a needle [48]. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the boss and needle hub, of the injector of the modified device of Jangula and Sempere, with threads, as taught by Pizzino, as such will provide a means for the attachment of a needle to an injector and will provide a means to prevent re-use of a needle as a new needle will be screwed onto the injector for every use of the injector (column 2, lines 63-68 to column 3, lines 1-8).

6. Claims 20 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jangula and Sempere, as applied to claims 1 and 21 above, and further in view of Brunnberg et al and Pizzino.

In regards to claim 20, with a modified device of Jangula and Sempere, Jangula teaches a method of using a handling device, as claimed in claim 1, with a medical injector [90] having a cylindrical body provided with a boss at the forward end thereof for supporting a needle/needle hub and a needle sheath [92] surrounding and protecting the needle, comprising the steps of:

- a. pushing the carrier [10] on to the forward end of the injector [90] so that the injector body is slidably received in the cylindrical sleeve [46], the boss carrying the needle hub is received in the bore [33][44] of the bushing [30][40], the sheath [92] is coupled to the inner tube [52], and the sheath [92] engages the plug [12] and pushes the plug [12] forwardly to project from the carrier [10] (paragraphs [0027][0028])
- b. pulling the carrier [10] away from the cylindrical body of the injector [90] with the sheath [92] retained within the inner tube [52] (paragraph [0028])

and following the performance of an injection:

- a. pushing the carrier [10] once more on to the forward end of the injector [90] and refitting the sheath [92] on to the needle (paragraph [0028])

Jangula does not teach that the injector [90] has an externally threaded boss for supporting the internal threads of a needle hub of a needle. Pizzino teaches an injector (Figure 1, syringe [10]) having a boss (externally screw threaded tubular conduit [46]) with external screw threads that are co-operable with the internal screw threads of a hub (internally screw threaded hub [52]) of a needle [48]. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the boss and needle hub, of the injector of the modified device of Jangula and Sempere, with threads, as taught by Pizzino, as such will provide a means for the attachment of a needle to an injector and will provide a means to prevent re-use of a needle as a new needle will be screwed onto the injector for every use of the injector (column 2, lines 63-68 to column 3, lines 1-8).

Jangula does not teach that on subsequent withdrawal of the carrier [10] from the injector [90], the bushing [30][40] and sleeve [46] remain on the injector. Sempere teaches a handling

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device (Figures 1-6) that is connected to a medical injector (syringe [4]) in which on withdrawal of a carrier (external cover [9]) of the device, a bushing (body [2]) and sleeve (body [1]) of the device remain on the injector [4]. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the bushing and sleeve, of the modified device and method of Jangula and Sempere, to remain upon the injector upon withdrawal of the carrier, as taught by Sempere, as the needle of the injector, subsequent to removal of the sheath from the needle, will be protected by the shielding effect of the bushing and sleeve upon the injector (Figure 1), before and after the injector is used (column 1, lines 4-12).

Jangula does not teach rotating the carrier to detach the needle hub from the boss and freeing the carrier from the injector body with the needle and sheath carried therewithin and pressing the projecting plug back into the carrier, so driving the sheathed needle out of the handling device. Brunnberg et al a handling device [10] for an injector, wherein the carrier of the handling device [10] is rotated to detach a needle hub from an injector (paragraph [0043]) and a projecting plug [54] is pressed back into the carrier to drive the sheathed needle out of the handling device (paragraph [0044]). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to incorporate steps of detaching the needle from the injector and disposing of the needle from the handling device, as taught by Brunnberg et al, into the modified device and method of Jangula and Sempere, as such will provide means for preventing the re-use of a used needle and will prevent contamination to the environment by a used needle.

In regards to claim 32, with a modified device of Jangula and Sempere, Jangula teaches a method of using a handling device, as claimed in claim 21, with a medical injector [90] having a cylindrical body provided with a boss at the forward end thereof for supporting a needle/needle hub and a needle sheath [92] surrounding and protecting the needle, comprising the steps of:

- a. pushing the carrier [10] on to the forward end of the injector [90] so that the injector body is slidably received in the cylindrical sleeve [46], the boss carrying the needle hub is received in the bore [33][44] of the bushing [30][40], the sheath [92] is coupled to the inner tube [52], and the sheath [92] engages the plug [12] and pushes the plug [12] forwardly to project from the carrier [10] (paragraphs [0027][0028])
- b. pulling the carrier [10] away from the cylindrical body of the injector [90] with the sheath [92] retained within the inner tube [52] (paragraph [0028])

and following the performance of an injection:

- a. pushing the carrier [10] once more on to the forward end of the injector [90] and refitting the sheath [92] on to the needle (paragraph [0028])

Jangula does not teach that the injector [90] has an externally threaded boss for supporting the internal threads of a needle hub of a needle. Pizzino teaches an injector (Figure 1, syringe [10]) having a boss (externally screw threaded tubular conduit [46]) with external screw threads that are co-operable with the internal screw threads of a hub (internally screw threaded hub [52]) of a needle [48]. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the boss and needle hub, of the injector of the modified device of Jangula and Sempere, with threads, as taught by Pizzino, as such will provide a means for the attachment of a needle to an injector and will provide a means to prevent re-use of a needle as a

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new needle will be screwed onto the injector for every use of the injector (column 2, lines 63-68 to column 3, lines 1-8).

Jangula does not teach that on subsequent withdrawal of the carrier [10] from the injector [90], the bushing [30][40] and sleeve [46] remain on the injector. Sempere teaches a handling device (Figures 1-6) that is connected to a medical injector (syringe [4]) in which on withdrawal of a carrier (external cover [9]) of the device, a bushing (body [2]) and sleeve (body [1]) of the device remain on the injector [4]. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the bushing and sleeve, of the modified device and method of Jangula and Sempere, to remain upon the injector upon withdrawal of the carrier, as taught by Sempere, as the needle of the injector, subsequent to removal of the sheath from the needle, will be protected by the shielding effect of the bushing and sleeve upon the injector (Figure 1), before and after the injector is used (column 1, lines 4-12).

Jangula does not teach rotating the carrier to detach the needle hub from the boss and freeing the carrier from the injector body with the needle and sheath carried therewithin for disposal. Brunnberg et al a handling device [10] for an injector, wherein the carrier of the handling device [10] is rotated to detach a needle hub from an injector (paragraphs [0043][0044]). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to incorporate a step of detaching the needle from the injector for disposal, as taught by Brunnberg et al, into the modified device and method of Jangula and Sempere, as such will provide means for preventing the re-use of a used needle and will prevent contamination to the environment by a used needle.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Freundlich et al (US 5,067,949), Barrelle (US 6,776,777), and Steiner et al (US 4,955,865).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEFALI D. PATEL whose telephone number is (571) 270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767